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JUN 16 2003
TC 1700

REMARKS

Entry of the foregoing and reexamination and reconsideration of the subject application, as amended, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested in light of the remarks which follow.

As indicated in the Office Action Summary, claims 1-54 are pending in the instant application. Claims 28-54 stand withdrawn as directed to non-elected subject matter. Applicants gratefully acknowledge that claims 7-27 stand allowed. Applicants further acknowledge the withdrawal of the rejections of claims 10-14 under 35 U.S.C. § 112, second paragraph, and of claims 1-9 under 35 U.S.C. § 103(a) over Tso *et al.*

New claim 55 is added by way of the present Amendment. Support for claim 55 may be found in original Claim 1 which is directed to a tobacco leaf which has been treated with a wash solution prior to being cured and then air cured. Prior to air curing the tobacco leaf is uncured and in a condition of having been contacted with a wash solution comprising an aqueous solution of a carbonate or bicarbonate salt.

New Rejections under 35 U.S.C. § 102(b) and § 103(a)

Claims 1-6 stand rejected under 35 U.S.C. § 102(b) as purportedly anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as purportedly obvious over Poulouse *et al.* (U.S. Patent No. 4,716,911).

Rejection under 35 U.S.C. § 102(b)

"[A]nticipation requires the presence in a single prior art disclosure of all elements of a claimed invention as arranged in the claims." *Jamesbury Corp. v. Litton Industrial Products, Inc.* 225 U.S.P.Q. 253, 256 (Fed. Cir. 1985). Poulouse *et al.* do not describe or suggest all of the elements of the rejected claims, as discussed in greater detail below.

Independent Claim 1 is directed to a tobacco leaf in a condition of having been contacted with a wash solution comprising an aqueous solution of a carbonate or bicarbonate salt and in a further condition of having been subsequently air cured. Applicants submit that the tobacco leaf defined in Claim 1 is not disclosed by Poulouse *et al.*

In the Office Action, Poulouse *et al.* is cited for purportedly disclosing a tobacco product resulting from a process in which cured tobacco leaves have been contacted with an amount of aqueous alkali (*i.e.*, carbonate salts). Thus, the finished product of Poulouse *et al.* is purportedly identical to the claimed tobacco leaf.

Applicants submit that the tobacco leaf product of Claims 1-6 is not disclosed or suggested by the tobacco leaf produced by the method of Poulouse *et al.* Specifically, the tobacco leaves recited in Claims 1-6 are washed in an aqueous solution of a carbonate or bicarbonate salt before they are cured. In contrast, Poulouse *et al.* disclose using alkali or a combination of protease or nonprotease depolymerases on the tobacco after it is cured. This results in the following differences in the end tobacco leaf products.

Bacterial populations on tobacco leaves are known to grow linearly or exponentially during traditional curing practices. Bacterial populations can increase by 10 to 20 fold

during curing. The bacteria reduce nitrates to nitrites, creating nitrosamines, and often leave behind bacterial endotoxins, which can remain even after the bacteria are destroyed. Claims 1-6 are directed to tobacco leaves treated with an antibacterial lavage before curing. Not only does the wash destroy bacteria on the leaves, it also raises the pH of the leaves. Raising the pH aids in reducing and eliminating nitrite levels. Thus, the tobacco leaves as claimed have greatly reduced or no tobacco specific nitrosamines (TSNAs) and endotoxins. This is because the wash destroyed the bacteria prior to the onset of conditions during curing, which are extremely favorable to bacterial growth and TSNA production.

In contrast, the leaves of Poulose *et al.* are treated with alkali or a combination of protease or nonprotease depolymerases after the tobacco is cured. Poulose *et al.* is concerned with extracting protein from cured tobacco without affecting the flavor. The tobacco leaves of the finished product do not have a reduced amount of TSNAs or endotoxins. Instead, the tobacco leaves of Poulose *et al.* merely have proteins extracted and retain certain aspects of the original tobacco flavor. Thus, the claimed tobacco leaves and the tobacco leaves of Poulose *et al.* are not identical.

New Claim 55 is presented herein, and is directed to a tobacco leaf in a condition of having been contacted with a wash solution comprising an aqueous solution of a carbonate or bicarbonate salt. The combination of features recited in Claim 55 is not disclosed or suggested by Poulose *et al.*

Rejection under 35 U.S.C. § 103(a)

As set forth in M.P.E.P § 2142, in order to establish a *prima facie* case of obviousness, three criteria must be met, *i.e.*, (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings, (2) there must be a reasonable expectation of success, and (3) the prior art references must teach or suggest all the claim limitations.

In the present case, 1) there is insufficient motivation to modify Poulouse *et al.* in the manner proposed in the Official Action, 2) there is no reasonable expectation of success of achieving the claimed tobacco leaf when modifying Poulouse *et al.*, 3) Poulouse *et al.* teach away from the claimed invention and 4) Poulouse *et al.* do not teach or suggest all of the claim limitations.

1) There is insufficient motivation to modify Poulouse et al.

The Office Action further asserts that when the art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternately on either section § 102 or § 103 is appropriate. Specifically, the Office Action alleges that Poulouse *et al.* is cited for purportedly disclosing a process in which cured tobacco leaves have been contacted with an amount of aqueous alkali (*i.e.*, carbonate salts), and thus the finished product of Poulouse *et al.* is purportedly identical to the claimed tobacco leaf.

Applicants submit that the skilled artisan, upon reading Poulouse *et al.*, would not have been led to create a tobacco leaf with reduced or absent TSNAs and/or bacterial

endotoxins. Specifically, Poulouse *et al.* disclose using alkali or a combination of protease or nonprotease depolymerases on the tobacco after it is cured, in order to extract proteins from tobacco leaves without compromising the flavor. Poulouse *et al.* fail to disclose or suggest the claimed tobacco leaf having reduced or no TSNAs or endotoxins.

Moreover, Poulouse *et al.* do not suggest that adjusting the pH or adding an alkali solution, for any reason, would result in a reduction of TSNAs and bacterial endotoxins in the tobacco. Thus, it is submitted that the skilled artisan would not have been motivated to modify Poulouse *et al.* in a manner which would result in the claimed invention.

2) There is no reasonable expectation of success of achieving the claimed invention when modifying Poulouse et al.

It is further submitted that the skilled artisan would not have had a reasonable expectation of success of achieving the claimed invention when modifying Poulouse *et al.*, because Poulouse *et al.* do not teach or suggest to the skilled artisan that adding alkali solution would result in a reduction of TSNAs and bacterial endotoxins in the tobacco.

3) Poulouse et al. teach away from the claimed invention

Poulouse *et al.* teach away from the claimed invention. The tobacco leaves of Claim 1 have significantly reduced TSNAs and bacterial endotoxins as a result of washing tobacco leaves in an alkali aqueous solution before curing. In contrast, Poulouse *et al.* instructs the skilled artisan to treat the leaves using the alkali solution on the leaves to obtain an extract of biomass, and then to treat the biomass with bacterial microorganisms to retain flavor.

Thus, Poulouse *et al.* lead the skilled artisan away from the claimed invention, instructing them to use microorganisms to retain tobacco flavor, rather than attempting to eradicate microorganisms from the tobacco leaf.

4) Poulouse et al. fail to teach or suggest each element of the claimed invention

Applicants further submit that Poulouse *et al.* fail to render the claimed invention obvious, because Poulouse *et al.* fail to teach or suggest each and every element of the claimed invention. The combination of features recited in Claim 1 is directed to a tobacco leaf which has been contacted with a wash solution comprising an aqueous solution of carbonate or bicarbonate salt, and then which is subsequently cured.

Thus, as a result, the tobacco leaf product of Claims 1-6 is not the same tobacco leaf as that produced by the method of Poulouse *et al.* Specifically, the claimed tobacco leaves are washed in an aqueous solution of a carbonate or bicarbonate salt before they are cured. In contrast, Poulouse *et al.* disclose using alkali or a combination of protease or nonprotease depolymerases on the tobacco after it is cured. This results in unobvious differences in the end products, as discussed above.

Accordingly, the claimed invention is patentable over Poulouse *et al.*

Unexpected Results

The Office Action asserts that in the event that any differences can be shown for the product of the product-by-product claims, as opposed to the product as taught by the reference, such differences would have been obvious to one of ordinary skill in the art as a

routine modification of the product in the absence of a showing of unexpected results.

Applicants respectfully submit that unexpected results are in fact present with respect to the claimed tobacco leaf.

It is a well established legal precedent that the presence of an unexpected, advantageous or superior result is evidence of nonobviousness. *See* M.P.E.P. § 716.02(a); *In re Papesch*, 315 F.2d 381, 137 U.S.P.Q. 43 (C.C.P.A. 1963). Along these lines, it is also well established that "a greater than expected result" is evidence of nonobviousness. *See* M.P.E.P. § 716.02(a); *In re Corkill*, 711 F.2d 1496, 226 U.S.P.Q. 1005 (Fed. Cir. 1985).

Applicants submit that the tobacco leaf recited in Claim 1 provides surprising and unexpected results in reducing tobacco-specific nitrosamines and bacterial endotoxins. Applicants have discovered that tobacco-specific nitrosamines and bacterial endotoxins can be reduced in tobacco leaves by washing the leaves with an alkaline solution before curing. Further, Applicants surprisingly discovered that the treatment of tobacco leaves with an aqueous solution of carbonate or bicarbonate anions prior to curing will accelerate the coloring of the tobacco during curing. Finally, Applicants unexpectedly discovered that when this treatment is coupled with immediate drying of the tobacco at the conclusion of the curing process, there are pronounced reductions in tobacco-specific nitrosamines and bacterial endotoxins in tobacco. *See* the present specification, page 13, line 28 to page 14, line 12. Thus, any *prima facie* case of obviousness based on Poulouse *et al.* is rebutted by such unexpected results.

Therefore, it is submitted that Poulose *et al.* fail to render the claimed invention obvious because there is insufficient motivation to modify Poulose *et al.*, there is no reasonable expectation of success of achieving the claimed method when modifying Poulose *et al.*, the cited reference teaches away from the claimed method and Poulose *et al.* fail to teach or suggest each and every element recited in claim 1. Further, Applicants' claimed invention achieves surprising and unexpected results. Thus, Applicants respectfully request withdrawal of this rejection.


CONCLUSION

In view of the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order. Such action is earnestly solicited.

In the event that there are any questions relating to this application, it would be appreciated if the Examiner would telephone the undersigned attorney concerning such questions so that prosecution of this application may be expedited.

Respectfully submitted,

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Date: June 13, 2003